Otto Bock
ORTHOPEDIC INDUSTRY, INC.

MAR - 8 2000

# 510(k) SUMMARY
# of
# SAFETY and EFFECTIVENESS

## General Information

| | |
|---|---|
| *Submitter's Name:* | Otto Bock Orthopedic Industry, Inc. |
| *Address:* | 3000 Xenium Lane North<br>Minneapolis, MN 55441 |
| *Telephone:* | 612-553-9464 |
| *Contact Person:* | John Hendrickson |
| *Date Prepared:* | February 10, 2000 |
| *Registration Number:* | 2182293 |

## Device

| | |
|---|---|
| *Name:* | Voyager/Viper Wheelchair |
| *Trade Name:* | Voyager/Viper Wheelchair |
| *Common Name:* | Manual Wheelchair |
| *Classification Name:* | Manual Wheelchair |
| *Product Code:* | IOR |
| *Class:* | I |
| *Regulation Number:* | 890.3850 |



Otto Bock Orthopedic Industry, Inc.
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## C. Identification of Legally Marketed Devices

1. *Name:* Champion 3000
2. *K Number:* K953428
3. *Date Cleared:* July 31, 1995

## D. Description of the Device

The Voyager/Viper is a lightweight, open-frame, manual wheelchair for active users. The wheelchair is manufactured in Königsee, Germany, at a production facility of the OTTO BOCK Group. The Voyager/Viper is sold in Europe as the 'Voyager' and will be sold/marketed in the United States as the 'Viper.'

The Viper has an 85° knee bend and is constructed of aluminum with seat widths of 13" to 18" and seat depths of 13" to 18".

## E. Intended Use Statement

The Voyager/Viper is an ultra-lightweight, open-frame wheelchair for active users. These wheelchairs provide mobility to physically challenged persons. The wheelchair can be moved by the user propelling the hand rims, which are attached to the rear (drive) wheels. The wheelchair can also be pushed by an assistant grasping the handles attached to the back rest.

## F. Technological Characteristics Summary

The Voyager/Viper Wheelchair is substantially equivalent to the Champion 3000 Wheelchair, cleared on July 31, 1995 as K953428.

Each wheelchair is a lightweight, open-frame, manual wheelchair for the active user, with a rigid frame, adjustable back, 85° knee bend and similar seat width, seat depth, and weight.

The Voyager/Viper was tested by TÜV Product Service to the following standards:

- EN 292
- prEN 12182
- prEN 12183
- EN/ISO 10993
- EN/ISO 9999
- ISO 7176-1

- ISO 7176-8
- ISO 7176-11
- ISO 7176-3
- ISO 7176-16
- ISO 7176-15
- EN 1041

with the conclusion that "there are no reservations concerning the use of this wheelchair for its intended use."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2000

Mr. John Hendrickson
President
Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K000497
Trade Name: Voyager/Viper Manual Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: February 10, 2000
Received: February 15, 2000

Dear Mr. Hendrickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number:** *To be determined* K000497

**Device Name:** Voyager/Viper Manual Wheelchair

**Indications for Use:**

- Provide mobility to persons physically challenged and limited to sitting positions

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

NRO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000497

Prescription Use _____ OR OVER-THE-COUNTER USE X
(optional Form 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000497